

## **REMARKS**

### Introductory Comments

Reconsideration of the present application in view of the above amendments and arguments set forth herein is respectfully requested.

Claims 17-27 are pending and under consideration. Claims 17 and 21 have been amended as explained below. No new matter has been added as a result of these amendments.

### Objection to the Specification

The specification is objected to for improperly incorporating by reference the cited patents. Specifically, the Examiner states that Applicants cannot use the omnibus language in the incorporation by reference language on pages 9 and 37 since they fail to teach with detailed particularity just what information Applicants seek to incorporate and where in the reference this information is located.

Applicants have previously respectfully traversed this objection first raised in a previous Office Action, but the Examiner has maintained this objection to the specification despite the detailed reasons previously provided by Applicants as to the inappropriateness of the objection.

First, it should be appreciated that Applicants' invention is not a device limited to one particular test or sample, but is a device which may be advantageously used with a range of tests and samples. To provide the detailed parameters for all possible tests within the present specification would unnecessarily clutter the application with information which is secondary to the invention and may be readily found elsewhere. This is essentially precisely the type of situation in which incorporation by reference is to be advantageously used.

Further, recently added 37 C.F.R. § 1.57 is instructive as to what Applicants believe to be the erroneous application of the rules in making this

objection. Specifically, providing clear guidance on the rule cited in the Office Action that “[m]ere reference to another application, patent, or publication is not an incorporation of anything therein”, 37 C.F.R. § 1.57(b)(1) specifies that an incorporation by reference must “[e]xpress a clear intent to incorporate by reference using the root words “incorporat(e)” and “reference” (e.g., “incorporate by reference”). Applicants have clearly met that requirement.

It is also significant that this new rule requires that that such specific language be used, and that the incorporation “[c]learly identify the referenced patent, application, or publication”, 37 C.F.R. § 1.57(b)(2), but nowhere does it specify that particular portions of the identified material be pointed out. Moreover, the rule defines “essential material” as material necessary to meet the first paragraph of 35 U.S.C. 112, and notes that this can be accomplished by reference to U.S. patents (as has been done here). C.F.R. § 1.57(c)(1).

Presently, other than a general objection to the form of the incorporation, it is not clear what disclosure is believed by the Examiner to be missing so as to make the “written description of the *claimed* invention” inadequate (see 37 C.F.R. § 1.57(c)(1)). For that reason, it is believed that this issue may, in any event, be nothing more than an intellectual exercise. Of course, even to the extent that the claims as developed during the prosecution of this application may make incorporated disclosure “essential material”, such incorporation is sufficient if made to a U.S. patent or U.S. patent application publication (37 C.F.R. § 1.57(c)), which the incorporation herein has done. Moreover, even if incorporation by reference is deemed to be inappropriate such that the disclosure should be included in the text of the application, it may be corrected by adding the incorporated disclosure by amendment (37 C.F.R. § 1.57(f)). In any event, given that the form of the claims has not yet been finally determined, Applicants believe it to be inappropriate to delete (incorporated) disclosure at this point.

Finally, Applicants wish to point out that in the vast majority of cases in which material is incorporated by reference, such incorporation is made of the entire document being referenced and not to specific portions thereof. Despite that, this is the first time the undersigned can recall receiving such a rejection.

Accordingly, Applicants respectfully request withdrawal of the objection to the specification.

Rejection of Claims 17-27 Under 35 U.S.C. § 112, Second Paragraph

Claims 17-27 are rejected under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which Applicants regard as the invention.

The Examiner states that the claims fail to correspond in scope with that which Applicants regard as the invention because the original disclosure, including the original claims, the specification, the title and the abstract all describe methods of processing a sample instead of a device for processing a sample as in the instant claims.

Applicants respectfully traverse this rejection.

The instant application is a continuation-in-part of U.S. Patent application 415,796, filed on October 11, 1999, as set forth on the first page of the specification. While the original application may focus on the method of processing a sample, the original application also clearly discloses a device for processing a sample. The device is amply described in the specification including the 61 figures.

However, in an effort to expedite prosecution of the instant application, Applicants have amended the title, the abstract and the summary to particularly point out the device for processing a sample as claimed. Support for these amendments can be found directly in the instant claims and throughout the specification. No new matter has been added as a result of these amendments.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter which Applicants regard as the invention.

Rejection of Claims 17-27 Under 35 U.S.C. § 112,

First Paragraph – Written Description

Claims 17-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It is alleged that these

claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action (paragraph 8) asserts that the claimed invention is a broad genus of devices which can comprise "an infinite number of 'containers' and where any magnitude of current and/or voltage can be applied."

This is not true of the claims as amended. That is, while no numerical limitations are included in the claims for container size, or current and/or voltage magnitude, the claims do now specifically recite that the container, conductors and circuit "are configured so that", *inter alia*, the voltage facilitates amplification and determination. Thus, the claims are limited to the present invention and do not cover an "infinite number" of structures.

Moreover, the specification provides an adequate written description of the claimed limited genus of devices. The Examiner's attention is drawn, for example, to page 56, lines 16-26 of the application, where it is disclosed that the parameters such as voltage may be optimized to provide desired molecular behavior such as lysis, elution and/or fragmentation (*i.e.*, amplification), and further provides a specific suitable example ("a voltage (V1) substantially within the range of about 2 to about 100 volts DC, a voltage pulse period (Tp) substantially within the range of about 0.5 to about 1000 milliseconds, a High Voltage Pulse Minimum Duty Cycle (Tmin) of about 5%, a High Voltage Pulse Maximum Duty Cycle (Tmax) of about 95%, and a Pulse Train Duration (Td) substantially within the range of about 1 to about 300 seconds").

In short, the present invention relates to a device and the disclosure of suitable example conditions fully show possession of such invention by Applicants at the time the application was filed. The format of the claims as amended, which do not inappropriately limit the scope of the invention to the numerical limitations of a particular example but nevertheless limit the claimed structure to cover what is also more broadly described, is thus now submitted to be appropriate. Further, to the extent that disclosure of further parameters may be found only in the incorporated references, the refusal in the Office Action to

accept such material (paragraphs 9-10 of the Office Action) to support the disclosure is believed to be improper as already noted above.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Rejection of Claims 17-27 Under 35 U.S.C. § 112,

First Paragraph - Enablement

Claims 17-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is based on the previously discussed written description rejection.

Applicants respectfully traverse this rejection based on the arguments set forth above pertaining to the written description rejection. For conciseness, Applicants incorporate those arguments by reference without repeating them herein.

With respect to the *Wands* factors relating to undue experimentation, the Office Action does not discuss in particularity each factor in relation to the instant disclosure. However, Applicants respectfully submit that the biotechnology art has come a long way and rapidly matured with specificity. The relative skill in the art is high and the state of the prior art is such that the methods of amplification and determination of DNA and RNA are well described and understood in the art. It is the methods of amplification and determination of DNA and RNA that the Examiner is questioning instead of the device according to the present invention.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Rejection of Claims 17-25 and 27 Under 35 U.S.C. § 102(b)

Claims 17-25 and 27 are rejected under 35 U.S.C. § 102(b), as being anticipated by Wilding *et al.*, U.S. Patent No. 5,587,128 (hereinafter "Wilding").

Specifically, the Examiner states that Wilding, at column 18 bridging column 19, discloses a device comprising multiple chambers that allow amplification of nucleic acids as well as electrophoretic separation and detection of amplicons or templates. The Examiner further states that the aspect of conducting electrophoresis speaks directly to the existence of a first and a second conductor and circuitry for controlling the voltage.

Applicants respectfully traverse this rejection.

The present invention is directed to a device for amplifying and determining a DNA or RNA comprising a container configured to hold a sample comprising nucleic acids, a first conductor, a second conductor, a circuit configured to control and provide voltage across the first conductor and the second conductor, wherein the voltage is applied to the sample in the container through the first conductor and the second conductor and facilitates the *amplification* and determination of the DNA or RNA. The analyzer is configured to adjust the voltage to reduce an ability of the biological element that is amplified in a PCR reaction process (page 2, lines 17-19 and page 3, lines 4-6), to remove the biological element from a binding member (page 2, lines 24-26 and page 3, lines 7-13) or to unzip the biological element (page 2, lines 30-31 and page 3, lines 14-18).

Wilding discloses a device for amplifying polynucleotides that contains a composition in the wall of a reaction chamber in order to enhance the amplification (abstract and column 5, line 27 to column 6, line 8). Wilding discloses electrophoresis only as a conventional means for separating polynucleotides from reactants and other components in the sample and *not for amplification* (see especially column 19, lines 13-15).

Lodish *et al.* (*Molecular Cell Biology, Fourth Ed.*, 2000, W.H. Freeman and Company, page 87) describes electrophoresis as such:

“Electrophoresis is a technique for separating, or resolving molecules in a mixture under the influence of an applied electric field. Dissolved molecules in an electric field move, or migrate, at a speed determined by their charge:mass ratio. For example, if two molecules have the same mass and shape, the one with the greater net charge will move faster toward an electrode. The

separation of small molecules, such as amino acids and nucleotides, is one of the many uses of electrophoresis. In this case, a small drop of sample is deposited on a strip of filter paper or other porous substrate, which is then soaked with a conducting solution. When an electric field is applied at the ends of the strip, small molecules dissolved in the conducting solution move along the strip at a rate corresponding to the magnitude of their charge."

Thus, electrophoresis is simply a method of *separating* the different contents, such as specified polynucleotides from other contents in a sample. The entire process and any voltage that are applied *do not involve the amplification* of the polynucleotides.

Wilding does not disclose or suggest a device for amplifying and determining a DNA or RNA comprising a container configured to hold a sample comprising nucleic acids, a first conductor, a second conductor, a circuit configured to control and provide voltage across the first conductor and the second conductor, wherein the voltage is applied to the sample in the container through the first conductor and the second conductor and facilitates the *amplification* and determination of the DNA or RNA.

In an effort to expedite prosecution of the instant application, Applicants have amended claim 17 such that it is clear that the claimed device is configured to directly apply a voltage difference during the amplification process. Specifically, Applicants have amended claim 17 to recite "wherein said container, said first conductor, said second conductor and said circuit are configured so that the voltage is applied to the sample in said container through said first conductor and said second conductor and facilitates the amplification and determination of the DNA or RNA." Support for this amendment can be found as noted *supra*. Claims 17 and 21 have also been amended to place the claims in a better form by inserting "and" in claim 17, and inserting "wherein" and changing "comprises" to "comprising" in claim 21. No new matter has been added as a result of these amendments.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-25 and 27 under 35 U.S.C. § 102(b), as being anticipated by Wilding *et al.*, U.S. Patent No. 5,587,128.

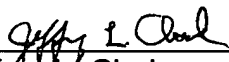
### CONCLUSION

Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 112 and 102. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, he is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Respectfully submitted,  
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